

The calculation of utilization increases reflects the change in the aggregate number of prescriptions filled. The calculation of annual increase in expenditures reflects the change in expenditure from an old set of drugs to a new set. To estimate the impact of pipeline drugs, case scenarios were performed around HCFA's baseline projections for future drug trends. The compounded, annual, growth-rate decrease of new drug approvals was used as a lower bound, while a constant increase in the pipeline projection provided the upper bound.

RESULTS: Historically, slightly less than one-third of the increase in drug expenditure was due to price increases on existing drugs, approximately one-third was due to increases in the utilization of existing drugs, and slightly more than one-third was due to product shift. Based on our data, the historical increase in expenditures was 15% for all drugs, 25% for newer drugs and 7% for older drugs. Our lower and upper bound scenarios projected national drug expenditures of \$191.56 billion and \$215.62 billion, respectively, for 2004.

CONCLUSION: The impact of pipeline drugs on future drug trends is significant. There is considerable variation surrounding the impact of pipeline drugs on future drug expenditures based on several plausible scenarios.

CANCER II

CN4

THE IMPACT OF THE DIAGNOSIS OF CANCER ON OUT-OF-POCKET HEALTH-CARE EXPENDITURES MADE BY THE US ELDERLY

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If the "total" costs of a disease, such as cancer, are to be accurately quantified, out-of-pocket expenditures (OOPE) made by patients and caregivers must be added to costs incurred by third party payers (direct medical) and employers (lost productivity). Prior studies of OOPE by the elderly used small geographically restricted samples and narrow patient subgroups.

OBJECTIVES: To rigorously quantify OOPE for individuals older than 70 years in the United States. To emphasize cancer-related OOPE, three patient cohorts were examined: 1) no cancer (No CA); 2) history of cancer but not undergoing treatment (CA/No Tx), and 3) undergoing active cancer treatment (CA/Tx).

METHODS: Data from the Asset and Health Dynamics Study, a nationally representative, longitudinal survey of community-dwelling elderly were used. Respondents denoted cancer status and reported OOPE over two years for: 1) nursing home/hospitals; 2) doctor visits; 3) prescription drugs, and 4) "special" services. Using a multi-variable two-part regression model to control for differ-

ences in co-morbidity, health status, living situation, and sociodemographics, the additional cancer-related OOPE was estimated.

RESULTS: Of the 6576 respondents, 5553 (84%) reported No CA, 843 (13%) reported CA/No Tx, and 180 (3%) reported CA/Tx. Cancer diagnosis and current cancer treatment were significant predictors of increased OOPE compared to no cancer. The mean annual OOPE for No CA, CA/No Tx, and CA/Tx groups was US\$1900, US\$2400, and US\$3300, respectively ($p < .001$). Hospitals (US\$1400/yr) and prescription drugs (US\$1100/yr) were the largest OOPE components for the CA/Tx group. The incremental OOPE for CA/No Tx and CA/Tx patients approximates US\$1.5 billion annually.

CONCLUSIONS: OOPE for elderly individuals with a history of cancer or ongoing therapy are substantial and significantly greater than for those without cancer. If OOPE remain unaccounted for, total costs of cancer will be consistently underestimated. Economic evaluations of interventions aimed at cancer prevention and treatment must account for OOPE.

CN5

A SPECIFIC QUALITY OF LIFE SCALE IN UPPER LIMB LYMPHOEDEMA: THE ULL-27 QUESTIONNAIRE

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OBJECTIVE: The aim of this study was to validate a self-completed questionnaire in Upper Limb Lymphoedema.

METHODS: A qualitative survey was conducted to identify patients' complaints. This questionnaire was administered to 154 patients. Principal component analysis was used to identify dimensions. A validation study was conducted in 304 patients. Six instruments have been used in the case report form: volume differences between the healthy and the affected arms; composite symptom scales completed by clinicians from patient interviews; ULL-27 and SF-36 scales completed by patients; overall opinion of doctors and patients. Internal validity was checked through factorial analysis. Trait validity was investigated by correlating the domains rated with ULL-27 with the SF-36 scale. Nomologic validity was tested by comparing the means of the ULL-27 subscales across severity stages. Sensitivity was tested only in patients with progressive disease between D0 and D28 by comparing mean sub-scores for the ULL-27 scale and by calculating the effect size.

RESULTS: Three hundred four patients were included in the study. Factorial analysis isolated three dimensions: physical (15 items), psychological (7 items), and social withdrawal (5 items). The Cronbach coefficients are greater than 0.80 for all dimensions. The Spearman correlations clearly distinguish the different life domains from each other. At D0 the physical and social dimensions of ULL-27 scale were significantly correlated with severity of illness but it was not the case for the psycho-